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Application No.: 10/735,602 **BEST AVAILABLE COPY**

Docket No.: JCLA10516

REMARKSPresent Status of the Application

The Office Action rejected claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al. (WO/94/24263) in view of Bhat et al. (J. Appl. Genet. 2001, 42(4): 405-412).

Applicant has amended claims 1 and 11 to more clearly define the present invention. The amendments to claims 1 and 11 are fully supported by the specification (for example, see page 8, lines 6-11), and no new matter is added. Claims 8 and 13 are canceled. After entry of the foregoing amendments, claims 1-7, 9-12, and 14-15 remain pending in the present application, and reconsideration of those claims is respectfully requested.

Rejection under 35 U.S.C 103 (a)

*Applicant respectfully traverses the 103(a) rejection of claims 1-15 because the combination of Bellhouse and Balt fails to teach every element recited in these claims.*

The present invention is in general related a method for delivering a biological material using a gene gun and a method for gene transformation by using a gene gun respectively as claims 1 and 11 recite:

Claim 1. A method for delivering a biological material using a gene gun, comprising:  
providing the gene gun comprising a pressurized chamber, a sprayer, a controller valve and a material delivery system;  
*placing a homogeneous liquid sample solution* into the material delivery system, wherein the sample solution comprises at least the biological material;

**BEST AVAILABLE COPY**

Application No.: 10/735,602

Docket No.: JCLA10516

*triggering the gene gun and providing a gas through the controller valve to the pressurized chamber until the gas establishes a pressure lower than 4 atm;*

releasing the sample solution from the material delivery system, so that the sample solution is accelerated by the gas in the pressurized chamber; and

discharging the sample solution out of the sprayer, wherein the sprayer includes a spray nozzle and a spray tube, and the spray nozzle comprises an interior contour, wherein the interior contour of the spray nozzle comprises a diverging part and a converging part and the spray tube is a diverging straight tube, so that a discharge speed of the sample solution is supersonic and the biological material is evenly injected into a target, and *wherein a pressure at the sprayer's outlet is about 1 atm.*

Claim 11. A method for gene transformation by using a gene gun, comprising:

providing the gene gun comprising a pressurized chamber, a sprayer, a controller valve and a material delivery system;

*placing a homogeneous liquid sample solution into the material delivery system*, wherein the sample solution comprises at least a nucleic acid;

*triggering the gene gun and providing a gas through the controller valve to the pressurized chamber to establish a pressure lower than 4 atm*, wherein the gas is a nitrogen gas or a helium gas;

releasing the sample solution from the material delivery system after the gas in the pressurized chamber establishes the pressure, so that the sample solution is accelerated by the gas in the pressurized chamber; and

discharging the sample solution out of the sprayer, wherein the sprayer includes a spray nozzle and a spray tube, and the spray nozzle comprises an interior contour, wherein the interior contour of the spray nozzle comprises a diverging part and a converging part and the spray tube is a diverging straight tube, so that a discharge speed of the sample solution is supersonic and the biological material is evenly injected into a target, and *wherein a pressure at the sprayer's outlet is about 1 atm.*

Applicant respectfully submits both Bellhouse and Bhat fails to disclose, teach or suggest the sample used in the delivery system is a homogeneous liquid sample solution, as recited in the amended claims 1 and 11.

Bellhouse discloses the delivery system is used for particles delivery in the citation. In particular, Bellhouse teaches, at page 2, lines 17-24, "Drug delivery by liquid jet causes skin

**BEST AVAILABLE COPY**

Application No.: 10/735,602

Docket No.: JCLA10516

damage and bleeding and offers no advance over needles in preventing the spread of blood-borne diseases. Thus, the main advantages which flow from the invention include no needle and less pain; no risk of infection delivery of drugs in natural, solid form; quicker and safer to use than liquid drug, by syringe and needle; and no sharps to dispose of". Bellhouse also teaches, at page 12, lines 29-32, "a particular advantage of the new technique of injecting dry powdered drugs is that it can be used for delivering a stable mixture of drugs, which are unstable when mixed wet". That is, the delivery system of the citation is not suitable for homogeneous liquid sample solution delivery.

In the Bhat reference, the sample is a suspension which is a mixture of water and gold particles, and it is not a homogeneous liquid sample solution. As shown in Table 1 on page 408, tungsten and gold particles of the size 0.6 and 1.6  $\mu$  (gold) and 1.0  $\mu$  (tungsten) are used as microcarriers in the sample. Therefore, applicant submits the two references fail to teach the sample is a homogeneous liquid sample solution. While in the present invention as defined in claims 1 and 11, a homogeneous liquid sample solution is delivered by using the gene gun, and thus micro-carriers (gold particles or tungsten particles) are not needed.

Furthermore, Bellhouse and Bhat also fail to disclose, teach or suggest that the pressured chamber is provided with a pressure lower than 4 atm, but higher than 1 atm. The amended claims 1 and 11 specify that the pressure at the sprayer's outlet is about 1 atm. Therefore, inherently the pressure in the pressured chamber is higher than 1 atm.

## BEST AVAILABLE COPY

Application No.: 10/735,602

Docket No.: JCLA10516

Bellhouse teaches, at page 7, lines 16-17, "burst pressures of 42, 61 and 100 atmospheres produced penetration depths of 38, 50 and 70 units respectively". In other words, the pressure established in the delivery system of the citation is much higher than 4 atm.

The method of the device disclosed in J. Appl. Genet. 2001, 42(4):405-412 is operated in a vacuum condition (28 mm-Hg, shown in Table 1 and see (<http://www.oardc.ohio-state.edu/plantranslab/PIG.htm>)).

Applicant respectfully submits that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine two references' teachings as proposed because the device used in the reference (J. Appl. Genet. 2001, 42(4):405-412) is much different from the device used in the reference WO 94/24263. In particular, the sample used in the reference (J. Appl. Genet. 2001, 42(4):405-412) is a suspension which is a mixture of water and gold particles while the sample used in the WO 94/24263 is a particle sample.

Furthermore, it is believed that the proposed combination is improper. Bellhouse requires, at page 7, lines 16-17, "burst pressures of 42, 61 and 100 atmospheres produced penetration depths of 38, 50 and 70 units respectively". While the method of the device disclosed in J. Appl. Genet. 2001, 42(4):405-412 is operated in a vacuum condition. Without the required high pressure, Bellhouse's method would not work. It is improper to combine references where to modify the primary reference would "destroy its structural identity and mode of operation." *Ex parte Jackson*, 146 USPQ 409, 410 (PTO Bd. App. 1964). It is improper to combine references if "do so would destroy that on which the inventions is based". *Ex parte Hartman*, 186 USPQ 336, 367 (PTO Bd. App. 1974)(2588)

For at least the foregoing reasons, Applicant respectfully submits that independent claims 1 and 11 patently define over the prior art references, and should be allowed. For at least the

JAN 16 2007

**BEST AVAILABLE COPY**

Application No.: 10/735,602

Docket No.: JCLA10516

same reasons, dependent claims 2-7, 9-12 and 14-15 patently define over the prior art as a matter of law, for at least the reason that these dependent claims contain all features of their respective independent claim.

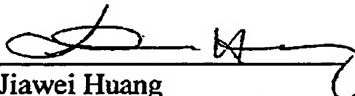
**CONCLUSION**

For at least the foregoing reasons, it is believed that the pending claims are in proper condition for allowance. If the Examiner believes that a telephone conference would expedite the examination of the above-identified patent application, the Examiner is invited to call the undersigned.

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